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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,667	10/29/2003	Mark L. Pomeranz	CRD5038	6834

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EXAMINER	
DOWE, KATHERINE MARIE	
ART UNIT	**PAPER NUMBER**
3734	

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09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,667	POMERANZ ET AL.	
	Examiner	Art Unit	
	Katherine M. Dowe	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,9-17,19,20,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,9-17,19,20,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a complete response to the amendment filed 6/29/2007.

2. Claims 1, 4-7, 9-17, 19, 20, 29, and 30 are currently pending.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 4-7, 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 5,342,348) in view of Rioux et al. (US 6,981,964). Kaplan discloses the invention substantially as claimed including a medical device (Figs 1-3) comprising an expandable stent (2) which takes the form of a hollow tubular member comprised of an expandable wire frame (col 4, lines 48-51), having a small diameter (col 4, lines 51-56), a relatively thin wall, and a plurality of cells (Fig 1A, element 10) formed by a plurality of interconnected strut members (8 and 6) (col 11, lines 12-14). Kaplan discloses the device further comprises a plurality of elongated removable slat members (14 and 16) interwoven between a plurality of the strut members (col 3, lines 36-39; col 6, lines 21-26; col 25, lines 25-33; col 11, lines 16-18) to temporarily attach the removable slat to the tubular member and provide a cover for a major portion of the peripheral surface of the tubular member (Fig 1A).

However, Kaplan does not disclose the removable slat members have tethers attached. Rioux et al. disclose a stent (Fig 16, element 50) with a portion (78) that may be removed by pulling a removal tether (80), or an elongated activation member,

selectively attached to that portion (col 16, lines 45-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Kaplan to include tethers, or an elongated activation members, attached to each removable slat acting as elongated puller wires such that the tethers could be selectively pulled to selectively remove the slats if the slats need to be removed during surgery. Furthermore, since Kaplan discloses the slat members (14 and 16) should be biodegradable such that they are removable when they are no longer useful, it would be obvious to make the added tethers biodegradable, and thus removable, as well such that they will not have to be removed by an additional surgery when they are no longer useful.

5. Claims 16, 17, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 5,342,348) in view of Masters et al. (US 2006/0167540) and Rioux et al. (US 6,981,964). Kaplan discloses the invention substantially as claimed including a medical device (Figs 1-3) comprising an expandable stent (2) which takes the form of a hollow tubular member comprised of an expandable wire frame (col 4, lines 48-51), having a small diameter (col 4, lines 51-56), a relatively thin wall, and a plurality of cells (Fig 1A, element 10) formed by a plurality of interconnected strut members (8 and 6) (col 11, lines 12-14). Kaplan discloses the device further comprises a plurality of elongated removable slat members (14 and 16) interwoven between a plurality of the strut members (col 3, lines 36-39; col 6, lines 21-26; col 25, lines 25-33; col 11, lines 16-18) to temporarily attach the removable slat to the tubular member and

provide a cover for a major portion of the peripheral surface of the tubular member (Fig 1A).

However, Kaplan does not disclose there is a second inner stent. Masters et al. disclose a medical device with an inner stent inserted into an outer stent (para 0001). Thus, an outer stent can have material that functions well with the vessel while the inner stent has material used to treat the vessel (para 0202), furthermore the outer stent may be smooth to interact harmlessly with the vessel, while the inner stent may aid in gripping a delivery catheter (para 0207). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kaplan to include an inner stent coaxially disposed within the outer stent similar to the outer stent provided, and thus the inner stent should have a plurality of slats interwoven through it. The inner stent provides additional drug delivery capacity such that the outer stent may provide therapeutic agents designed for the vessel wall, while the inner stent provides therapeutic agents designed for the vessel lumen. Thus, more area is covered by the stent to apply the therapeutic agent from on the slat members more evenly about the vessel wall and lumen.

Furthermore, Kaplan does not disclose the removable slat members have tethers attached. Rioux et al. disclose a stent (Fig 16, element 50) with a portion (78) that may be removed by pulling a removal tether (80) selectively attached to that portion (col 16, lines 45-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Kaplan to include tethers, or elongated activation members, attached to each removable slat acting as elongated

puller wires such that the tethers could be selectively pulled to selectively remove the slats if the slats need to be removed during surgery. Furthermore, since Kaplan discloses the slat members (14 and 16) should be biodegradable such that they are removable when they are no longer useful, it would be obvious to make the added tethers biodegradable, and thus removable, as well such that they will not have to be removed by an additional surgery when they are no longer useful.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 5,342,348) in view of Hoganson et al. (US 2003/0074049). Kaplan discloses the invention substantially as claimed including a medical device (Figs 1-3) comprising an expandable stent (2) which takes the form of a hollow tubular member comprised of an expandable wire frame (col 4, lines 48-51), having a small diameter (col 4, lines 51-56), a relatively thin wall, and a plurality of cells (Fig 1A, element 10) formed by a plurality of interconnected strut members (8 and 6) (col 11, lines 12-14). Kaplan discloses the device further comprises a plurality of elongated removable slat members (14 and 16) interwoven between a plurality of the strut members (col 3, lines 36-39; col 6, lines 21-26; col 25, lines 25-33; col 11, lines 16-18) to temporarily attach the removable slat to the tubular member and provide a cover for a major portion of the peripheral surface of the tubular member (Fig 1A). Furthermore, Kaplan discloses the expandable stent is inserted into a blood vessel of a patient (col 9, lines 31-47).

However, Kaplan does not disclose the stent is used to treat aneurysms. Hoganson et al. disclose a method of treating aneurysms within a bifurcated vessel with

a stent covered with a polymer capable of releasing drugs or other therapeutic agents (pg 1, para 0002). The stent has an expandable tubular frame (Fig 19, element 10), a cover member (22) carried by the tubular frame, and including a detachable portion (220). The covered stent is inserted into a blood vessel and positioning the stent such that is aligned with and covering an aneurysm in the blood vessel (Fig 29). The detachable portion is removed from the cover portion by withdrawing the detachable portion from the vessel thereby allowing blood to flow through a portion of the cover member of the covered stent at the location of the detachable portion and into surrounding blood vessels (para 0125 and 0129-0131). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaplan such that the stent was used to treat aneurysms and such that the removable slats were selectively removed to provide flow to a branching blood vessel.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 5,342,348) in view of Hoganson et al. (US 2003/0074049), Masters et al. (US 2006/0167540), and Rioux et al. (US 6,981,964). Kaplan discloses the invention substantially as claimed including a medical device (Figs 1-3) comprising an expandable stent (2) which takes the form of a hollow tubular member comprised of an expandable wire frame (col 4, lines 48-51), having a small diameter (col 4, lines 51-56), a relatively thin wall, and a plurality of cells (Fig 1A, element 10) formed by a plurality of interconnected strut members (8 and 6) (col 11, lines 12-14). Kaplan discloses the device further comprises a plurality of elongated removable slat members (14 and 16)

interwoven between a plurality of the strut members (col 3, lines 36-39; col 6, lines 21-26; col 25, lines 25-33; col 11, lines 16-18) to temporarily attach the removable slat to the tubular member and provide a cover for a major portion of the peripheral surface of the tubular member (Fig 1A). Furthermore, Kaplan discloses the expandable stent is inserted into a blood vessel of a patient (col 9, lines 31-47).

However, Kaplan does not disclose the stent is used to treat aneurysms. Hoganson et al. disclose a method of treating aneurysms within a bifurcated vessel with a stent covered with a polymer capable of releasing drugs or other therapeutic agents (pg 1, para 0002). The stent has an expandable tubular frame (Fig 19, element 10), a cover member (22) carried by the tubular frame, and including a detachable portion (220). The covered stent is inserted into a blood vessel and positioning the stent such that is aligned with and covering an aneurysm in the blood vessel (Fig 29). The detachable portion is removed from the cover portion by withdrawing the detachable portion from the vessel thereby allowing blood to flow through a portion of the cover member of the covered stent at the location of the detachable portion and into surrounding blood vessels (para 0125 and 0129-0131). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kaplan such that the stent was used to treat aneurysms and such that the removable slats were selectively removed to provide flow to a branching blood vessel.

Additionally, Kaplan does not disclose there is a second inner stent. Masters et al. disclose a medical device with an inner stent inserted into an outer stent (para 0001). Thus, an outer stent can have material that functions well with the vessel while the inner

stent has material used to treat the vessel (para 0202), furthermore the outer stent may be smooth to interact harmlessly with the vessel, while the inner stent may aid in gripping a delivery catheter (para 0207). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kaplan to include an inner stent similar to the outer stent provided. The inner stent should have a plurality of slats interwoven through it and be coaxially disposed within the outer stent, such that the slat members are aligned to obtain a substantially continuous cover for the medical device. Thus, more area is covered by the stent to apply the therapeutic agent from on the slat members more evenly about the vessel.

Furthermore, Kaplan does not disclose the removable slat members have tethers attached. Rioux et al. disclose a stent (Fig 16, element 50) with a portion (78) that may be removed by pulling a removal tether (80) selectively attached to that portion (col 16, lines 45-47). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent of Kaplan to include tethers attached to each removable slat acting as elongated puller wires such that the tethers could be selectively pulled to selectively remove the slats if the slats need to be removed during surgery. The tethers would allow the surgeon to easily pull the removable slats out of the stent and simplify the procedure.

Response to Arguments

8. Applicant's arguments filed 6/29/2007 have been fully considered but they are not persuasive. Applicant argues the cited references do not teach an expandable stent

with a plurality of elongated removable slat members interwoven between the strut members to provide a cover for a major portion of the stent wall. The Examiner respectfully traverses the applicant's remarks. Applicant has not defined "major portion" and thus Kaplan's Figure 1A may be interpreted to have removable slat members covering a major portion of the stent. In addition, since the removable slats are arranged around the circumference of the stent, they can be interpreted to form a substantially continuous cover.

9. In response to applicant's argument that Rioux et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Rioux et al. teach the general concept of using a tether to remove elements from a stent, thus a slat member may be removed in the same manner the valve of Rioux et al. is removed, since both are elements incorporated into a stent. The slat members of Kaplan are interwoven through the stent and not fixed to the stent, thus the slat members are capable of being removed. Additionally, Kaplan discloses it is desirable to remove the slat members before the stent must be removed and thus the slat members are biodegradable. However, it would have been obvious to remove the slat members before they degrade should the need arise, for example if a patient does not need the full concentration of therapeutic agent. And Rioux et al. teaches a known method for removing elements from a stent while it is positioned in the body.

10. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
September 17, 2007

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER